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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE BIOGEN '755 PATENT LITIGATION	Civil Action No. 10-cv-02734 (CCC) (JBC) (consolidated)

MEMORANDUM OF LAW IN SUPPORT OF BAYER HEALTHCARE PHARMACEUTICALS INC.'S MOTION TO STRIKE THE UNTIMELY EXPERT REPORT OF DR. PASTOR COUCEYRO

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As the Court is aware, Biogen moved to strike the July 29 expert report of Dr. Gordon Moore, which demonstrates that claim 1 of the '755 patent—the only patent claim asserted against Bayer—is anticipated. Biogen based its motion on the claim that it was prejudiced by Dr. Moore's report because it was unable to do testing of its own. But unbeknownst to Bayer or the Court, during the very period that motion was briefed and argued, Biogen was performing such testing. Now—having apparently realized that it was unlikely to succeed in excluding this evidence that is fatal to its case—Biogen has changed strategy: it has served an untimely, second "supplemental" report responding to Dr. Moore's report. Biogen's attempt to claim prejudice and then, failing that, to turn around and produce the testing it claimed it was prejudiced by being unable to do, should not be countenanced. And even setting aside its misdirection, Biogen's untimely expert report would upend the schedule for this case and thereby prejudice Bayer. It should be excluded.

Bayer timely served Dr. Moore's report, accompanied by a complete disclosure of its own testing materials, on July 29. In response to Biogen's protestations, Bayer offered Biogen whatever time it needed to perform its own testing during the period when expert reports were being exchanged. Biogen conducted an in-person examination of Dr. Moore's materials with its own expert and requested samples of the DNA that he tested. But Biogen ultimately decided

to move to strike Dr. Moore's report and to serve a responsive report without its own testing. The parties negotiated multiple extensions to the deadline for Biogen to serve that responsive report, and Biogen served it on September 29. Expert depositions then began, and Dr. Moore was deposed on November 11. By that time, Biogen had taken three-and-a-half months to inspect and analyze Dr. Moore's experiments and data, obtain samples, and then examine him. Dr. Moore testified regarding his report and Biogen's responsive report.

Meanwhile, Biogen filed its motion to strike on October 11. As Bayer noted in its opposition brief, Biogen's brief was suspiciously precise regarding its effort to conduct testing: Biogen never said that it could not retain *any* lab to do its experiments, only that one lab had turned it down. The evidence is now clear that throughout the time that Biogen was impressing upon the Court that Dr. Moore's report should be stricken because Biogen could not perform experimental testing, it was in fact performing that testing. Its testing lab received samples—samples that were prepared in advance—and testing work was underway no later than *two days* after Biogen filed its opening brief and told the Court it was prejudiced. And when Biogen refused to answer the Court's question at the November 22 hearing about whether it wanted to continue trying to find a lab, it in fact *already had experimental results in hand*.

As the Court is aware from the parties' recent letters (ECF Nos. 479, 482),

Biogen on December 13 informed the Court of its experimental efforts for the first time and sought leave to serve what it acknowledged to be an untimely, second response to Dr. Moore's report on December 20, 2016. The Court did not grant Biogen's request for leave, so without leave or authority, Biogen arrogated to itself the power to adjust the Court's Scheduling Order and served the report at 11:57 pm on December 20.

Bayer received Biogen's second response to Dr. Moore's less than three days ago, but even from Biogen's limited disclosures, it is already clear that the experiments Biogen directed are deeply flawed. The materials Biogen provided suggest that, far from *replicating* Dr. Moore's experiment as Biogen claims, *see* ECF No. 485 at 2, Biogen dramatically and deliberately deviated from Dr. Moore's protocol in a manner designed to reduce the likelihood of observing a hybridization signal. Biogen's expert then unjustifiably attempts to draw a conclusion from the flawed experiments that the tested DNA did not hybridize under the conditions of Biogen's rigged experiment. But the extent to which these experiments are flawed will be impossible to ascertain on the schedule that Biogen, acting as both litigant and adjudicator, has sought to impose unilaterally. Biogen did not produce many of the most important materials regarding its experiment or even offer to make available any of the original materials underlying its work (Bayer has requested production and inspection of all of these materials, Fletcher Decl., Ex. C), yet it

suggests that Bayer should be prepared to depose on January 6 the report's signatory, Dr. Pastor Couceyro. Even when Bayer provided immediate inspection of Dr. Moore's materials upon request and timely produced all of the samples and other materials associated with the experiments, Biogen had 104 days to confer with its expert, conduct its own analysis of the experiments and data, request and take whatever discovery it deemed appropriate, and then examine Dr. Moore. Once Biogen produces all of the materials regarding its experiments—and it has not done so—fairness would dictate that Bayer be provided a commensurate amount of time to analyze the experiments and data, to examine the materials that were tested, and conduct any appropriate discovery before deposing Dr. Couceyro. Such a deposition would occur in April 2017.

Expert discovery closes on January 13, 2017; opening summary judgment briefs follow a mere few weeks later. For Bayer to have adequate time to analyze Biogen's results without disrupting the schedule is now impossible.

Biogen's report is thus several months too late. Its representations to the Court in moving to strike were dubious when made and now have been demonstrated to be (under the most charitable possible light) grossly and brazenly misleading. Biogen's effort to smuggle what appears to be flawed data into the case over the holidays is outrageous. The Court should strike Biogen's untimely report and preclude Biogen from relying on any of the opinions or data expressed

in that report.

I. LEGAL STANDARD

This Court's most recent scheduling order set forth a clear deadline of September 29, 2016, for service of responsive expert reports. ECF No. 447. Under the plain terms of Rule 37, "reports that are not disclosed in a timely manner are automatically excluded and may not be used 'to supply evidence . . . unless the failure was substantially justified or is harmless.'" *Paolino v. JF Realty, LLC*, 830 F.3d 8, 13 (1st Cir. 2016) (quoting Fed. R. Civ. P. 37(c)(1)); *see O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1368 (Fed. Cir. 2006) (courts "plainly ha[ve] the authority to exclude . . . untimely reports"); *Yeti By Molly, Ltd. v. Deckers Outdoor*, 259 F.3d 1101, 1106 (9th Cir. 2001) ("Rule 37(c)(1) gives teeth to" the time limits for disclosing expert reports "by forbidding the use at trial of any information required to be disclosed by Rule 26(a) that is not properly disclosed."). Because of this "automatic[]" exclusion, no order should even be necessary to exclude Biogen's improper and untimely report. *EON Corp. IP Holdings LLC v. FLO TV Inc.*, 2013 WL 5890571, at *3 (D. Del. Aug. 28, 2013). But equally clearly, Rule 37 favors "early preclusion of inadmissible evidence." *Id.* And while no further analysis should be necessary, Biogen is likely to argue that the factors set forth in *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904 (3d Cir. 1977), should apply here. These factors include

(1) "bad faith or willfulness in failing to comply with the court's order," (2) prejudice or surprise, (3) the ability to cure the prejudice, (4) the extent to which the untimely report "would disrupt the orderly and efficient trial of the case," and (5) the importance of the evidence to be excluded. *Reckitt Benckiser Inc. v. Tris Pharma, Inc.*, 2011 WL 6722707, at *6 (D.N.J. Dec. 20, 2011). Each of these factors supports striking Dr. Couceyro's untimely report, as described below.

II. ARGUMENT

A. Biogen Has Acted in Bad Faith By Willfully Ignoring the Court's Scheduling Order for Deadilnes on Serving Expert Reports.

Biogen acted in bad faith—and the first *Pennypack* factor is met, to the extent it applies—for two reasons.

1. The Court's operative scheduling order, ECF No. 447, is not ambiguous. It amended the deadline for responsive reports in this case, making any such reports due on September 27, 2016. This amendment was made because, among other reasons, Biogen requested more time to respond to Dr. Moore's report. *See id.* at 1 (second recital). Biogen informally requested a further extension of this deadline, to which Bayer agreed, and Biogen served a report responding to Dr. Moore from Dr. Pastor Couceyro on September 29, 2016.

In Biogen's December 13 letter, it recognized that the Court's existing Order did not permit it to serve another expert report to respond again to Dr. Moore. ECF No. 479 at 1. That is why Biogen offered "to withdraw its motion to strike if

it is permitted to serve a supplemental expert report from Dr. Pastor Couceyro. Biogen seeks leave to do so . . ." *Id.* Having not received the leave it acknowledged was required, Biogen went ahead and did what it wanted. It is hard to imagine a more flagrant case of willful disregard of the Court's scheduling order.

2. Biogen's representations to the Court over the past several months concerning its alleged prejudice and its plans to respond to Dr. Moore's report have been, at best, deliberately evasive. Bayer does not make this allegation lightly, but regretfully, even affording Biogen every benefit of the doubt, the record here permits no other conclusion. The materials Biogen appended to its untimely December 20 report, while incomplete, establish the following timeline.

- September 13. Bayer ships to Biogen samples of the DNA that Dr. Moore used in his experiments, including a sample of the DNA encoding interferon-α (referred to as "Clone 4").[1] ECF No. 482-6.

- September 14. Unknown to Bayer, Gene Art, a vendor that makes DNA synthetically, prepares "Clone 4" on behalf of Paul Weiss LLP. Fletcher Decl., Ex. A (Couceyro Report, Appendix H).

- September 22. Biogen informs Bayer that it "is no longer interested

[1] Bayer agreed to produce the samples far earlier, but Biogen had not provided an address to which they could be shipped. ECF No. 482-5.

in agreeing to an extension to perform experimental testing." ECF No. 482-8 at 1. Bayer responds that if Biogen is uninterested in performing its own testing, it should return Bayer's samples.

- October 5. Biogen returns to Bayer untouched the DNA samples that Bayer had provided, including Clone 4. ECF No. 482-10.

- October 11. Biogen files its motion to strike, arguing that "few contract laboratories . . . remain equipped" to perform the type of testing at issue, stating that it had contacted a lab that turned out to be unable to perform the testing, and intimating (but not stating) that it has been unable to find a lab that could replicate Dr. Moore's experiments. *See* ECF No. 457-1 at 14.

- October 13. The loose-leaf notes of Lofstrand Labs Limited state "Paul, Weiss . . . LLP Southern Blot project. Samples received 10/13/16." Fletcher Decl., Ex. B at unnumbered PDF page 1. Not having been produced (or apparently maintained) in a standard, bound laboratory notebook, there is no way to know if these are the first notes Lofstrand took. The notes do not indicate when Lofstrand Labs was retained, and Biogen has not produced any retainer agreement with Lofstrand Labs. It defies logic and common sense to imagine that Biogen filed its motion to strike on October 11 and the very next day, October 12, contacted Lofstrand Labs for the first time, negotiated a retainer agreement, and dispatched samples that were received by Lofstrand on October 13.

- October 25. Bayer files its opposition to the motion to strike, calling attention to the fact that "while Biogen describes its difficulty arranging testing with one laboratory capable of working with radioactive DNA labeling, it does not represent that it could not find a suitable lab." ECF No. 460 at 14.

- November 1. Biogen files its reply in support of its motion to strike. Biogen nowhere discloses that it has retained a lab or that it has testing in progress. *See* ECF No. 463. In fact, it does not respond at all to Bayer's observations about the fastidious-seeming wording of its motion. Biogen instead argues that, "The entire point of the case management schedule is to join issue and avoid surprises[.]" *Id.* at 5.

- November 11. Lofstrand completes first set of experiments. "Label, scan & email" the results, presumably to its client, Biogen's attorneys at Paul Weiss. Fletcher Decl., E. B at unnumbered PDF page 12.

- November 11. Biogen takes Dr. Moore's deposition.

- November 22. The Court hears argument on the motion to strike. The Court asks Biogen: "Are you still interested in looking for another lab?" ECF No. 482-12 (Hearing Transcript) at 124. Biogen does not state that it has retained Lofstrand Labs. Biogen does not state that Lofstrand Labs completed its experiment and transmitted the results more than a week ago. Biogen instead dithers, stating: "I think, your Honor, that we would be interested in seeing what --

is there some series of steps that we can do that we think puts us on an equal footing here, or as far as possible, with Bayer. And I mean, one way forward would be for us to think about that and then come back in the first instance I suspect to counsel for Bayer and ultimately to the Court and say, how about if we do this." *Id.* at 124-25.

- November 30-December 8. Lofstrand purports to perform the same experiment two more times, again deviating enormously from Dr. Moore's experiments. Fletcher Decl., Ex. B at unnumbered PDF pages 23-25.

- December 13. Biogen files a letter seeking leave to serve a second response to Dr. Moore's report. ECF No. 479. In the letter, Biogen tells the Court: "it bears noting that circumstances have changed since Biogen filed its Motion to Strike. Then [October 11, 2016], it seemed unlikely that Biogen could cure the prejudice caused by Bayer's untimely disclosure because Biogen could not find a laboratory to conduct the requisite Clone 4 experiments." *Id.* at 2 (date added). "Subsequently, however, Biogen was able to retain the services of a properly certified laboratory to perform the experiments on an expedited basis." *Id.* Biogen did not advise the Court that it had already identified a laboratory at the time it filed its Motion to Strike and represented to the Court that it was prejudiced "because Biogen could not find a laboratory to conduct the requisite Clone 4 experiments." As noted above, Biogen has not provided any record of the precise

date when it first contacted Lofstrand Labs to arrange for the testing (Bayer has requested this information). However, giving Biogen the benefit of the doubt, it did so simultaneously with filing its motion to strike (not "subsequently"), weeks before filing its reply brief that declined to mention that it had retained Lofstrand, and well over a month before it chose not to respond forthrightly to the Court's question as to whether it was "still interested in finding a lab" (at which point it already had received test results).

- December 20, 11:57 p.m. Biogen serves the second report of Dr. Couceyro responding to Dr. Moore despite having requested but not obtained leave to do so.

- December 23. Bayer meets-and-confers with Biogen regarding its untimely service of an expert report. Bayer indicates that it will move to strike the report, and proposes a briefing schedule for such a motion.

- December 23. Biogen pre-emptively dashes off a letter to the Court informing the Court that it has served a report without leave. ECF No. 485. The letter nowhere clarifies the timeline of Biogen's retention of Lofstrand Labs.

Biogen's actions at several points along this timeline are indicative of bad faith. Most troubling was Biogen's intimation throughout October and November that it was prejudiced by a purported inability to retain a lab—a suggestion that it appears to have conveyed successfully in view of the Court's question "Are you

still interested in looking for another lab?"—when it in fact *had retained a lab and had results in hand eleven days prior to the hearing*.

Even in its race-to-the-courthouse filing of December 23, Biogen continues to prevaricate. It writes: "If Bayer was under the impression that Biogen would not test Clone 4, it was not due to any explicit or implicit representation on the part of Biogen." ECF No. 485 at 2. This is false. Bayer memorialized the meet-and-confer negotiations that the parties had in September, and at that time noted that "We had a follow-up call this morning, Thursday, September 22, during which you informed me for the first time that Biogen is no longer interested in agreeing to an extension to perform experimental testing[.]" ECF No. 482-8 at 1. Biogen did not correct this statement and did not inform either the Court or Bayer, in the briefing or hearing on its Motion to Strike, that it had changed its mind and would seek to supplement the closed record with new experimental testing.

There can be no question that the standard of "bad faith" is far surpassed here. And in view of Biogen's conduct, there plainly is no substantial justification to excuse Biogen's violation of the Court's Order in serving an untimely report, as Rule 37 requires.

B. Forcing Bayer to Review Biogen's Experiments in Shortened Time is Prejudicial to Bayer.

Countenancing and rewarding Biogen's flagrant disregard for the Scheduling Order unsurprisingly would throw the schedule into chaos. To the

extent *Pennypack* applies, the next three factors—(2) prejudice or surprise, (3) the ability to cure the prejudice, (4) the extent to which the untimely report "would disrupt the orderly and efficient trial of the case"—thus all weigh in favor of granting the motion to strike.

Biogen's proposed schedule is simply unworkable. Biogen has proposed a deposition of Dr. Couceyro the first week of January—approximately two weeks after it served its report, over the holidays. Biogen's recent letter suggests that "Biogen would be happy to arrange a later deposition date," ECF No. 485 at 2, but no reasonable dates exist that would preserve the existing summary judgment and trial schedule.

Biogen suggests that Bayer's complaint of prejudice "is simply not credible" because "summary judgment motions are not due to be filed until the middle of February." *Id.* Not even this representation from Biogen, which it has advanced twice to the Court, in its letters of December 13 and December 23, can be trusted. Summary judgment motions are actually due on February 3, not in the middle of February. ECF No. 447 at 2.

Biogen also attempts to diminish Bayer's prejudice by arguing that the materials it served on December 20 consist of "11 pages of text and 39 pages of attachments." ECF No. 447 at 2. This page count entirely ignores the primary evidence, such as it is, of the experiment itself—it does not account for the

"materials considered" submitted with the report, which includes the collection of loose-leaf pages that purport to be the "lab notebook" generated by Lofstrand Labs.

But even if Biogen correctly tallied up the number of pages it served (and it did not), the paucity of its production is a bug, rather than a feature. That Biogen provided so little information demonstrates the prejudice to Bayer of requiring an immediate response, rather than refuting it. Quite simply, Biogen fails to address the more significant problem of what it *has not* served. Among other glaring deficiencies, Bayer has been unable to locate in the materials provided any copy of the experimental protocol used by Lofstrand Labs for the experiment, any copies of instructions provided by Biogen's counsel to Lofstrand Labs, or any data whatsoever associated with at least one of the experiments on which Dr. Couceyro relies. Biogen also has not provided access to the original photographic films generated in the experiments, only scans. Such access is necessary to confirm that the scans of the films that Biogen provided do not contain artifacts (and indeed that the purportedly negative results are indeed negative). Nor has Biogen provided samples of the reagents it tested to permit confirmation that they are what Biogen contends they are. At present, the record reflects that all of the samples were provided by the Paul Weiss law firm, not the original suppliers of the DNA. At present, Biogen can only argue that "the net addition to the subject matter of expert discovery in this case is minimal," ECF No. 485 at 2, because it has failed to

provide adequate supporting materials. Far from reducing prejudice, the fact that Biogen has produced so little documentation of its experiments requires that Bayer have more time before examining Dr. Couceyro, so that it may obtain those materials and analyze them in advance of his deposition.

The foregoing discovery and deposition of Dr. Couceyro may itself be insufficient. Bayer's initial review of Dr. Couceyro's report indicates that, unlike Dr. Moore, he did not supervise or observe the experiments about which he testified. Accordingly, to the extent he is unable to respond to various questions regarding the conduct of the experiments—a near certainty if he did not supervise them personally, in view of Lofstrand's apparent record-keeping practices—additional discovery may be necessary to understand the experiments and respond to them meaningfully.

By way of comparison, even when Bayer (unlike Biogen) produced with Dr. Moore's report all of the documentary evidence associated with his testing, and even when Bayer permitted inspection and agreed to furnish samples immediately upon request, Biogen was afforded three-and-a-half months (July 29 until November 11) to analyze the documents, the experiments, the data, and the samples before deposing Dr. Moore. During this time, it inspected the experimental materials and data, consulted with its experts and multiple laboratories, and performed software analysis of the data. Bayer intends to test the

samples Biogen has used in its experiments to confirm that they are what Dr. Couceyro contends that they are, once Biogen produces them, inspect and analyze the data with the assistance of its expert (who has two extended overseas trips in the next two months), and take whatever additional discovery it deems appropriate upon analysis of the materials it has requested. Biogen's suggestion that Bayer should be afforded less opportunity for analysis and discovery than Biogen—especially when Biogen's expert who served the report apparently did not even supervise the experiments on which he now belatedly relies—is unfair at best and outright disingenuous at worst. Either way, it is prejudicial.

Under the existing schedule, Bayer's summary judgment briefing is due on February 3, 2016. The expert deposition schedule was already extended into 2017 to accommodate Biogen's request for additional time to serve responsive expert reports. *See* ECF No. 447. Any further extension to the expert discovery period to provide Bayer a commensurate opportunity to analyze Biogen's supplemental report and take discovery would affect drastically the timeline for summary judgment, which would in turn require delaying Bayer's trial date, should trial be necessary and should it proceed against Bayer on the existing schedule.

Put simply, the calendar permits only three choices: (1) Biogen's untimely supplemental report must be stricken; (2) Bayer must be prejudiced by dramatically restricting its time to analyze and conduct discovery relating to the

report compared to what the Scheduling Order contemplated and Biogen itself got; or (3) Bayer (and Serono, unless Bayer is severed from Serono) must be prejudiced by a significant delay of the trial date. Fairness demands that Biogen's report be stricken.

C. Biogen Already Received Extensions to Respond to Dr. Moore's Report and Did So in September.

Even if the Court applies the *Pennypack* factors, the final factor—the importance of the evidence to be excluded—does not provide a basis to deny Bayer's motion. As explained above, Biogen's experimental testing does not in fact replicate Dr. Moore's testing and therefore cannot, as a matter of both fact and law, defeat the proposition that the sole claim asserted against Bayer is anticipated. Biogen recognized as much. Were it so clearly a response on the merits to Dr. Moore's results, one would imagine that Biogen would have shared the results with the Court when it had them in hand at the November 22 hearing. That Biogen did not reveal its efforts to conduct testing until after the Court suggested it might deny Biogen's motion to strike speaks volumes about the "importance" of Biogen's evidence.

Even if Biogen's new data were pertinent, however, courts have recognized that it is appropriate to strike an untimely expert report that contains "substantial new data and information that went well beyond the scope of [the expert's] opening report." *Id.* at *3; *Reckitt Benckiser Inc. v. Tris Pharma, Inc.*, 2011 WL

6722707 (D.N.J. Dec. 21, 2011). The parties already once negotiated an extended time for Biogen to respond to Dr. Moore's report, and it already responded on that extended schedule. Biogen's second response to Dr. Moore's report plainly extends beyond that initial response, and it should stricken.

III. CONCLUSION

For the reasons explained above and in Bayer's December 13, 2016, letter to the Court, Bayer respectfully requests that its motion to strike the untimely supplemental expert report of Dr. Couceyro be granted.

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